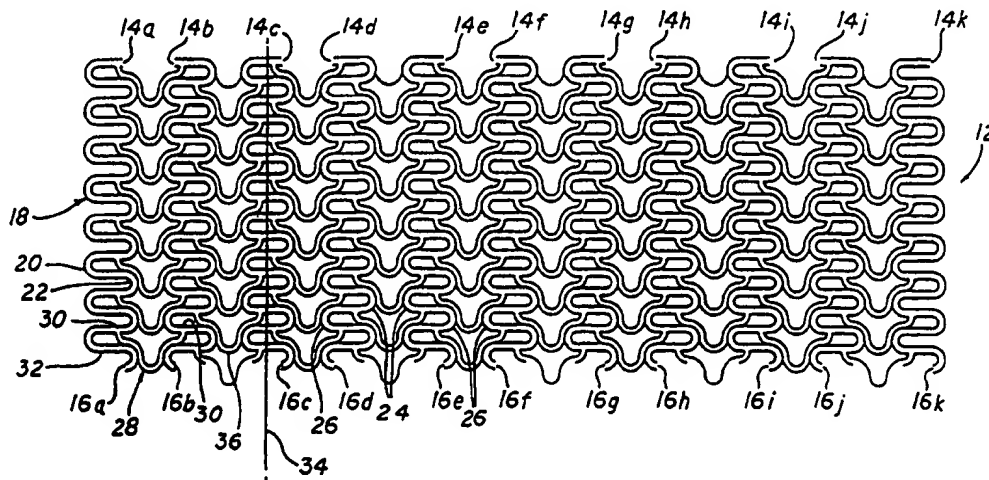




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<p>(21) International Application Number: PCT/US99/17053</p> <p>(22) International Filing Date: 28 July 1999 (28.07.99)</p> <p>(30) Priority Data: 09/124,376 28 July 1998 (28.07.98) US</p> <p>(71) Applicant: ADVANCED CARDIOVASCULAR SYSTEMS, INC. [US/US]; 3200 Lakeside Drive, Santa Clara, CA 95054-8167 (US).</p> <p>(72) Inventor: COX, Daniel, L.; 191 Washington Avenue, Palo Alto, CA 94301 (US).</p> <p>(74) Agents: MAHER, Pamela, G. et al.; Pulwider Patton Lee & Utecht, LLP, 10th floor, 10877 Wilshire Boulevard, Los Angeles, CA 90024 (US).</p>		<p>(81) Designated States: AE, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CU, CZ, DE, DK, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, UA, UG, UZ, VN, YU, ZA, ZW, ARIPO patent (GH, GM, KE, LS, MW, SD, SL, SZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG).</p> <p>Published <i>With international search report. Before the expiration of the time limit for amending the claims and to be republished in the event of the receipt of amendments.</i></p>

(54) Title: IMPROVED STENT CONFIGURATION



(57) Abstract

A stent having a series of circumferentially disposed serpentine elements linked to each another by bridging members that are connected to the serpentine elements at juncture points located along straight linking segments between adjoining apexes of the serpentine elements. The bridging elements are shaped such that during expansion of the stent, any longitudinal contraction experienced by the serpentine element is compensated for by the deformation of the bridging elements such that the overall length of the stent is maintained as substantially constant.

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IMPROVED STENT CONFIGURATIONBACKGROUND OF THE INVENTION

The present invention generally relates to intravascular stents and more particularly pertains to improvements thereto that provide for enhanced longitudinal flexibility, increased longitudinal stability upon radial expansion, and high strength.

Stents or expandable grafts are implanted in a variety of body lumens in an effort to maintain the patency of the lumens. These devices typically are implanted intraluminally by use of a catheter which is inserted at an easily accessible location and then is advanced to the deployment site. The stent initially is in a radially compressed or collapsed state to enable it to be maneuvered through the lumen. Once in position, the stent is deployed which, depending upon its configuration, is achieved either automatically or actively by, for example, the inflation of a balloon about which the stent is carried on the catheter.

As stents normally are employed to hold open an otherwise blocked, constricted or occluded lumen, a stent must exhibit sufficient radial or hoop strength in its expanded state to effectively counter the anticipated forces. Not only is it advantageous to distribute such loads over as much of the stent as possible but also it is most beneficial to distribute the load over as much of the lumen wall as is possible. As a consequence, it is desirable to maximize the coverage area of the stent in its expanded state. Simultaneously, however, it is necessary for the stent to be as small and compact as possible in its collapsed state in order to facilitate its advancement through the lumen. As a result, it is most advantageous for a stent to have as large as an expansion ratio as possible.

An additional consideration with stent design is the longitudinal flexibility of the device. Longitudinal flexibility is important not only in maneuvering the stent into position, which may require the traversal of substantial convolutions of the vasculature, but also to better conform the device to any curvature of the vasculature

at the deployment site. At the same time, however, it is necessary for the stent to nonetheless exhibit sufficient radial strength to provide the necessary support for the lumen walls upon deployment.

Another problem inherent in many prior art stent configurations is the longitudinal contraction that the stent structure typically undergoes as it is radially expanded. This longitudinal contraction not only reduces the effective length of the stent in its deployed state but also may cause abrasion trauma to be inflicted on the vessel walls during expansion.

A number of very different approaches previously have been devised in efforts to address these various requirements. A popular approach calls for the stent to be constructed wholly of wire. The wire is bent, woven and/or coiled to define a generally cylindrical structure in a configuration that has the ability to undergo radial expansion. Using wire to configure a stent has a number of disadvantages including, for example, the substantially constant cross-section of wire which may cause greater than or lesser than an ideal amount of material to be concentrated at certain locations along the stent. Additionally, wire only can be formed into a limited number of shapes and this therefore, limits the expansion ratio, coverage area, flexibility and strength that ultimately can be attained with a wire device.

As an alternative to wire-based structures, stents have been constructed from tube stock. By selectively removing material from tubular starting material, a desired degree of flexibility and expandability can be imparted to the structure. Chemical etching techniques as well as laser-cutting processes are used to remove material from the tube. Laser cutting provides for a high degree of precision and accuracy with which very well-defined patterns of material can be removed from the tube leaving behind very precise and accurately defined patterns of material. The performance of tube-based stents very much is a function of the pattern of material which remains. The selection of a particular pattern has a profound effect on the coverage area, expansion ratio and strength of the resulting stent as well as on the

longitudinal flexibility and longitudinal dimensional stability of the stent during expansion.

While the tube-based stents offer many advantages over the wire-based designs, it nonetheless is desirable to improve upon such designs in an effort to
5 further enhance longitudinal flexibility and longitudinal dimensional stability during radial expansion without the sacrificing radial hoop strength of the deployed device.

SUMMARY OF THE INVENTION

The present invention provides for an improved tube-based stent having enhanced longitudinal flexibility and longitudinal dimensional stability during radial
10 expansion while exhibiting adequate hoop strength upon deployment. The improvements derive from the selection of a precisely defined pattern of voids that are cut or etched into tube stock which is used to form the stent. After etching or cutting, the pattern of material that remains to define the stent comprises a series of generally parallel serpentine elements, wherein such elements are interconnected to
15 each another by advantageously shaped and positioned bridging members. More particularly, each serpentine element extends circumferentially about the stent such that successive apexes of each element alternatively extend distally and proximally along the stent's surface. The serpentine elements are successively spaced along the length of the stent and are oriented such that the pattern of apexes of each element is
20 180° out of phase relative to the pattern of apexes of each directly adjacent element. Each of the serpentine elements are joined to an adjacent element by at least one bridging member. The number, length and flexibility of the bridging members determines the longitudinal flexibility of the resulting device in its collapsed as well as in its deployed state. The attachment of the bridging members to juncture points
25 along the linking segments extending between the apexes causes the bridging members to distort during deployment. By matching the dimensional change

imparted to the length of the stent caused by the expansion of each serpentine element to the dimensional change along the same direction caused by the rotation and distortion of the bridging element, the overall length of the stent is held constant during deployment. Additionally, the spacing of the juncture points away from the
5 apices distributes the stress that otherwise would be concentrated at the apices during expansion of the device.

These and other features and advantages of the present invention will become apparent from the following detailed description of preferred embodiments which, when taken in conjunction with the accompanying drawings, illustrate by way of
10 example the principles of the invention.

BRIEF DESCRIPTION OF THE DRAWINGS

FIGURE 1 is a flattened, plan view of a section of an embodiment of a stent according to the present invention in its collapsed state.

FIG. 2 is a flattened plan view of a section of an alternative embodiment of
15 a stent according to the present invention in its collapsed state.

FIG. 3 is flattened plan view of a section of another alternative embodiment of a stent according to the present invention in its collapsed state.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

20 Embodiments of the present invention provide improved structural configurations for stents that serve to enhance the performance of the devices. Stents are introduced into the body and then advanced through the vasculature to be expanded at a deployment site in an effort to maintain the patency of the vessel at

such location. A stent according to the present invention offers a high degree of longitudinal flexibility prior to and upon deployment and then overall length remains substantially constant during deployment so as to avoid traumatization of the vessel tissue during deployment. Moreover, the deployed stent provides
5 sufficient radial hoop strength to enable it to withstand the loads imposed by the vessel it is intended to support.

The figures generally illustrate the invention and, more particularly, show three preferred embodiments thereof. The stents are shown in their pre-expanded or collapsed state. In each of the figures, the stent is shown in a longitudinally split
10 and flattened condition in order to enhance clarity and to aid in the understanding of the stent structure.

FIG. 1 illustrates one of the preferred embodiments of the present invention. As indicated above, the stent 12 is shown in a longitudinally parted and flattened condition. In actuality, points 14a-k are joined to points 16a-k, respectively, to
15 define a tubular structure. The stent consists of a plurality of serpentine elements 18 extending about the circumference of the stent. Each serpentine element has proximally-extending apexes 20 and distally-extending apexes 22 alternatingly arranged along its length. A plurality of such elements are assembled in parallel along the length of the stent wherein adjacent serpentine elements are arranged such
20 that the respective patterns of apexes are 180° out of phase. Consequently, apexes of adjacent serpentine elements alternatingly face in a direction 24 towards each another and face away in a direction 26 from each another. Adjacent serpentine elements are joined to one another by bridging members 28. In the embodiment shown, a maximum number of bridging members, namely eight, are employed to
25 join adjacent serpentine elements. A reduced number of such bridging members may be employed in order to increase the longitudinal flexibility of the stent, which is achieved primarily by freeing up the serpentine elements 18 upon removing some of the bridging members 28. In other words, if a bridging member is omitted, the

corresponding serpentine element is unsupported and unconstrained at the point of omission and therefore can expand and move more easily, which in turn results in greater longitudinal flexibility of the stent.

The bridging members 28 of the present invention are each joined to adjacent
5 serpentine elements at juncture points 30 positioned along the straight linking
segments 32 extending between the apexes. Such points are positioned not only to
avoid the highly stressed apex area but also are spaced apart from the centerline 34
of each serpentine element. More particularly, each bridging member is joined to
the linking segment on the side of the centerline closest to the serpentine element
10 being bridged by the bridging member. The bridging members are shaped such that
the change in separation of the ends of each bridging member that is caused by the
rotation and repositioning of the ends during deployment is offset by the change in
length of each bridging member resulting from deformation, such that a constant
overall stent length is maintained. Additionally, the inclusion of a curved portion 36
15 near the center of each bridging member allows the bridging member to expand
during stent expansion, which serves to enhance the flexibility of each bridging
member and hence the flexibility of the stent.

During the deployment of the stent, i.e., expansion, of the stent for example,
by the inflation of a balloon positioned within the interior of the stent, each of the
20 serpentine elements 18 stretches to accommodate the increase in circumference.
This stretching is achieved when the apexes 20, 22 bend, as a result of which, and in
contrast to the 180° curves shown in FIG. 1, each apex assumes a curvature of
something less than 180°, the actual magnitude of the curvature being dictated by
the extent to which the stent has been expanded. As each apex bends, the linking
25 portions 32 between apexes are caused to rotate, which forces the juncture points 30
to shift towards the centerline 34 of the serpentine elements. The distortion of the
bridging members 28 which results, namely, the opening up of the curved portion
36, results in a slight lengthening of the bridging member. This lengthening

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precisely compensates for the increase in the spacing of opposed juncture points which results from the distortion each serpentine element undergoes as it becomes stretched. As a result, the overall length of the stent remains substantially unchanged as the stent undergoes expansion. A shifting of the stent relative to the surrounding vessel walls thereby is avoided, so that trauma is not inflicted upon the surrounding vessel tissue. Additionally, because each juncture point is spaced away from its corresponding apex, stresses are distributed more independently during deployment. Moving the juncture point away from the apex probably does not reduce the stress in and of itself. What this positioning of the juncture point likely does do is to make the stresses of the apex more independent of those at the juncture. These stresses then can be manipulated more independently to reduce them individually as needed. Consequently, the stresses associated with the bending of the apex region and the stresses associated with the transfer of forces from the serpentine elements to the bridging members are separated from one another. By avoiding the concentration of stress, the stent is less prone to failure post-deployment.

FIG. 2 illustrates an alternative embodiment of a stent according to the invention. The tubular stent 40 again is shown in the parted and flattened state described above wherein all of the serpentine elements terminating along the edge 42 are shown severed from the serpentine elements terminating along the edge 44. Circumferentially-extending serpentine elements 46 are arranged in parallel along the length of the stent. Each serpentine element has a series of proximal apexes 48 and distal apexes 50 alternately extending along the surface of the stent, wherein each of the apexes are similarly shaped and dimensioned. Adjacent serpentine elements are arranged such that the respective patterns of apexes are 180° out of phase. The apexes of adjacent serpentine elements therefore alternately face towards each other and away from each other. The configuration and the juncture points 52 of the bridging members 54 render this particular embodiment

distinguishable from the embodiment illustrated in FIG. 1. More particularly, in FIG. 2, while each bridging member is joined to a linking segment 56 at a point that is set apart from the apex and from the centerline 58, such juncture point is located on the side of the centerline that faces away from the serpentine element to which the bridging member interconnects. Consequently, the juncture points in this particular embodiment are set much further apart from each another than are the juncture points in the embodiment shown in FIG. 1. Thereby, it is possible to accommodate a longer, bridging element in the stent configuration.

Each of the bridging members 54 includes a zig-zagging portion 60 near to the center thereof center which not only provides enhanced length, but also provides a configuration that will deform in a manner that will compensate for the shift in position that juncture point undergoes during expansion. The total number of bridging members may be reduced from the eight shown which will result in some distal apexes 50 being freed up and proximal apexes 48 which enhance the longitudinal flexibility of the stent both prior to and after deployment. As stated above, by removing a bridging member, corresponding serpentine elements are unsupported thereby primarily providing the increased flexibility in the stent.

During deployment, the stent 40 performs similarly to the embodiment shown in FIG. 1, in that each serpentine element 46 stretches via the bending of its apexes 48, 50. As the stent expands and the linking segments 56 rotate, each of the juncture point 52 pairs are brought closer together. The forces inherent in such repositioning cause the bridging members 54 and, more particularly the zig-zag portion 60 of each bridging member, to deform and to elongate so as to maintain a substantially constant overall length of the stent.

FIG. 3 illustrates yet another embodiment of the present invention. Circumferentially-extending serpentine elements 72 are again employed, but these elements differ from those shown in Figs. 1 and 2 insofar as the patterns defined along the distal and proximal edges of each serpentine element are irregular. In the

embodiment shown, two sets of two maximally-extended apexes 74 are separated by a single minimally extending apex 76, both on the proximal as well as distal edges of the serpentine element. Adjacent serpentine elements are again 180° out of phase and are spaced such that the maximally extending apexes of adjacent
5 serpentine elements preferably abut each another but do not necessarily have to abut. Each bridging member 78 is attached to a serpentine element at juncture points 80 that are located along the straight linking segment 82 and on the side of the centerline 84 closest to the serpentine segment that is bridged by the bridging member.

10 During deployment, the serpentine elements 72 stretch, which causes the juncture points 80 to shift towards the centerline 84 and away from each other. The bridging members 78 straighten, thereby increasing in length to compensate for the dimensional change caused by the shifting of the juncture points. The overall length of the stent 70 thereby substantially remains constant at all times.

15 The stents of the present invention preferably are formed using laser cutting techniques well known in the art and as disclosed in co-pending U.S. Serial No. 08/783,565. The material used in the manufacture of such stents may be a nickel titanium alloy (NiTi), stainless steel, tantalum, Pt/Ir, etc. After the appropriate shapes have been cut into the tube stock by the laser, the workpiece may be
20 subjected to an electropolishing operation to provide a smoothly finished device.

While a particular form of the invention has been illustrated and described, it will also be apparent to those skilled in the art that various modifications can be made without departing from the spirit and scope of the invention. Accordingly, it is not intended that the invention be limited except by the appended claims.

WHAT IS CLAIMED IS:

1. An expandable stent, comprising:
a series of circumferentially disposed serpentine elements, each such element including a series of apexes alternately extending proximally and distally relative to a circumferentially extending centerline defined by each said element,
5 successive apexes being joined by substantially straight linking segments, said serpentine elements being arranged along said stent such that each series of apexes is 180° out of phase relative to the series of apexes of adjacent serpentine elements; and
bridging members interconnecting adjacent serpentine element,
10 wherein each end of a bridging member is joined to a serpentine element at a juncture point located along said linking segment and offset from said centerline.
2. The stent of claim 1, wherein the bridging members are shaped to deform in such a way so as to compensate for any change in distance between juncture points interconnected by such bridging members which results from an expansion of the stent, in order to maintain the overall length of the stent substantially constant.
3. The stent of claim 1, wherein the juncture points of each bridging member are located between the centerlines of the two serpentine elements interconnected by the bridging member.

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4. The stent of claim 3, wherein each bridging member is shaped to increase in overall length during expansion of the stent in order to compensate for the increased separation of the juncture points.
5. The stent of claim 4, wherein each bridging member includes a U-shape.
6. The stent of claim 1, wherein the centerlines of two serpentine elements joined by a bridging member are located between the two juncture points of the bridging member.
7. The stent of claim 6, wherein the bridging element is shaped to decrease in overall length during expansion of the stent in order to compensate for the decreased separation of the juncture points.
8. The stent of claim 7, wherein the bridging member includes an S-shape.
9. The stent of claim 1, wherein some of the bridging elements have been removed to improve flexibility.

FIG. 1

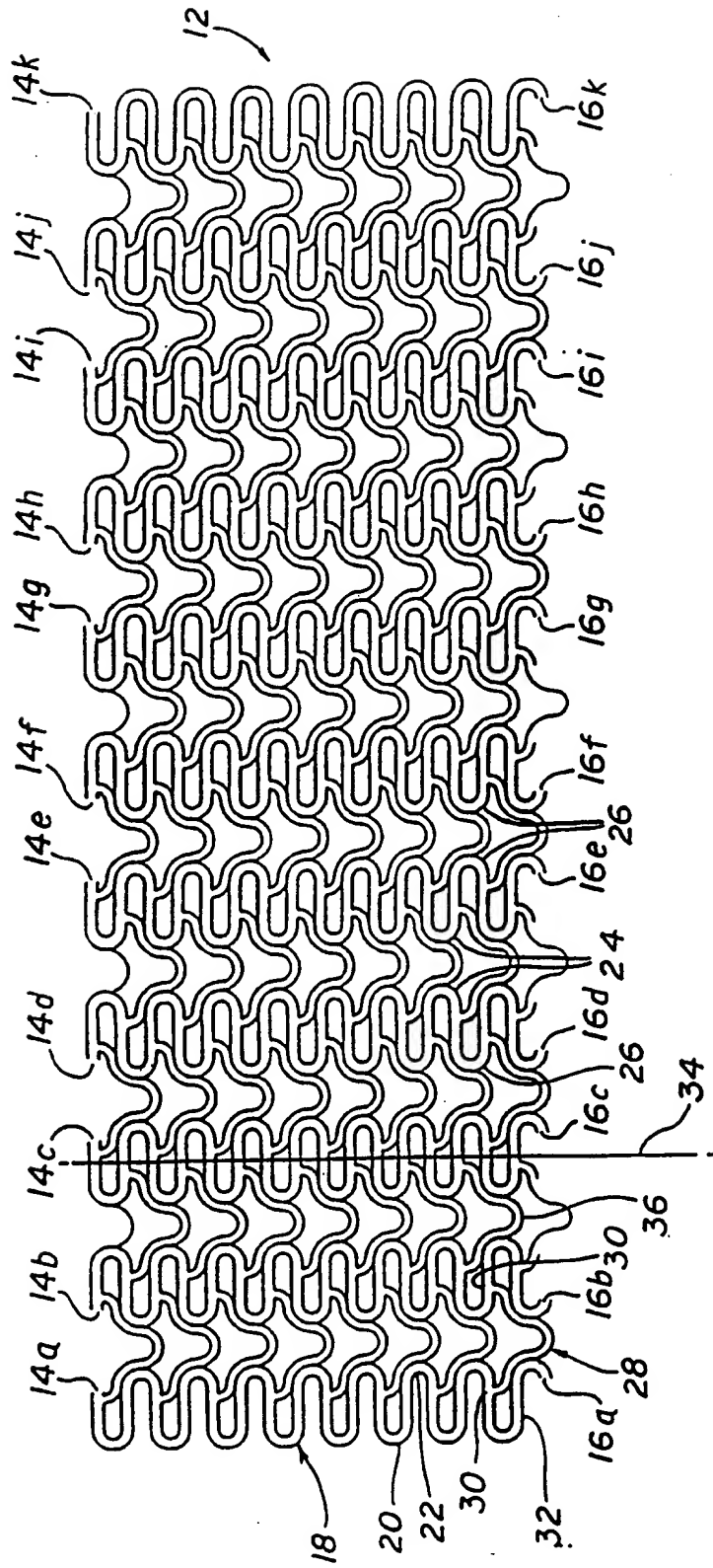


FIG. 2

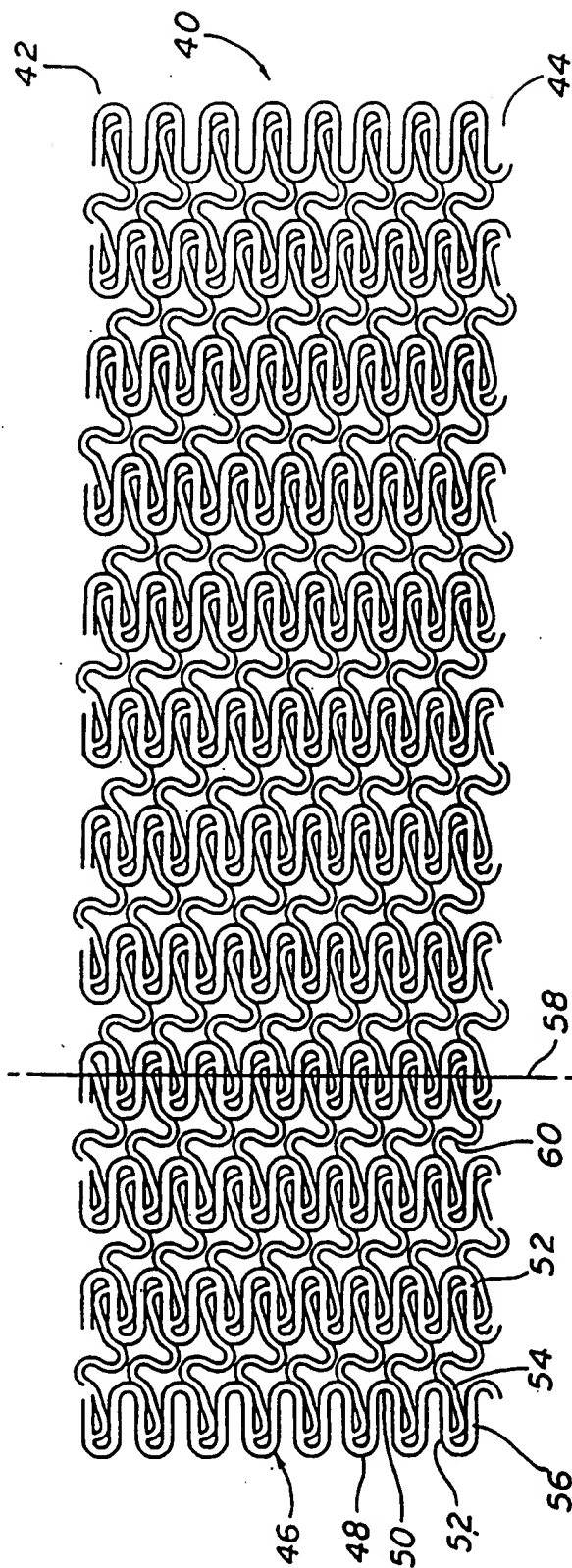
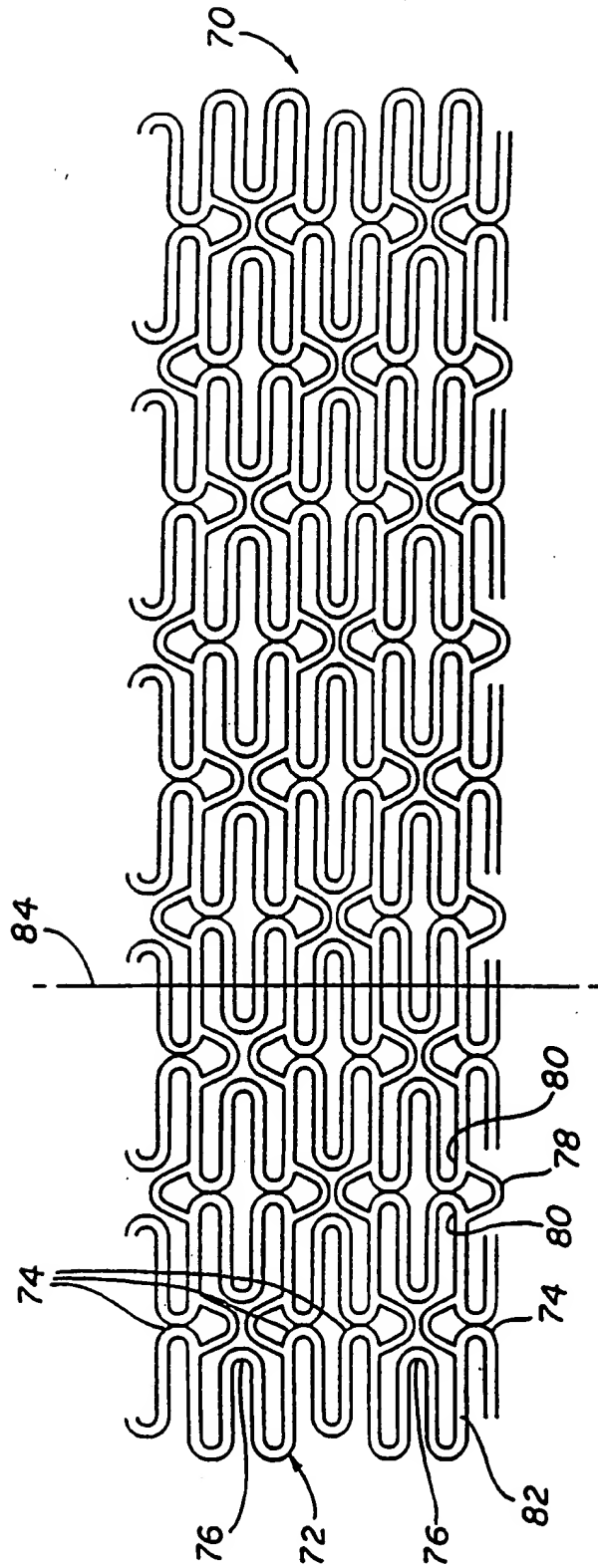


FIG. 3



INTERNATIONAL SEARCH REPORT

International Application No

PCT/US 99/17053

A. CLASSIFICATION OF SUBJECT MATTER

IPC 7 A61F2/06

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 7 A61F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the International search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	FR 2 758 253 A (NYCOMED LAB SA) 17 July 1998 (1998-07-17) claim 1; figure 1	1-5
X	WO 96 03092 A (MEDINOL LTD ;BRUN HEIDI M (IL)) 8 February 1996 (1996-02-08) page 6, line 33 -page 7, line 12; figures 1,2,5,7	1-5
A		9
P,X	WO 98 48733 A (SCIMED LIFE SYSTEMS INC) 5 November 1998 (1998-11-05) claim 12; figures 1,2	1-4

☐ Further documents are listed in the continuation of box C.

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Date of the actual completion of the international search

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information on patent family members

International Application No

PCT/US 99/17053

Patent document cited in search report		Publication date	Patent family member(s)	Publication date
FR 2758253	A	17-07-1998	EP 0951255 A	27-10-1999
			WO 9830172 A	16-07-1998
WO 9603092	A	08-02-1996	US 5733303 A	31-03-1998
			AT 170733 T	15-09-1998
			AU 3124699 A	05-08-1999
			AU 3124799 A	05-08-1999
			AU 702468 B	25-02-1999
			AU 3270695 A	22-02-1996
			BR 9508353 A	04-11-1997
			CA 2195783 A	08-02-1996
			CN 1158078 A	27-08-1997
			CZ 9700191 A	11-06-1997
			DE 19581503 C	02-04-1998
			DE 19581503 T	16-01-1997
			DE 29521193 U	24-10-1996
			DE 29521205 U	19-09-1996
			DE 29521206 U	19-09-1996
			DE 69504659 D	15-10-1998
			DE 69504659 T	06-05-1999
			DK 8097 A	19-02-1997
			EP 0762856 A	19-03-1997
			EP 0846448 A	10-06-1998
			EP 0846449 A	10-06-1998
			EP 0846450 A	10-06-1998
			EP 0846451 A	10-06-1998
			EP 0846452 A	10-06-1998
			ES 2123285 T	01-01-1999
			FI 970316 A	07-03-1997
			GB 2304587 A,B	26-03-1997
			GB 2315415 A,B	04-02-1998
			JP 10503676 T	07-04-1998
			LT 97022 A,B	25-11-1997
			LU 90031 A	16-04-1997
			NO 970289 A	26-03-1997
			NZ 291543 A	29-06-1999
			PL 318270 A	26-05-1997
			SE 9700206 A	28-02-1997
			SI 9520079 A	31-12-1997
			SK 11597 A	08-10-1997
			US 5972018 A	26-10-1998
			US 5843120 A	01-12-1998
WO 9848733	A	05-11-1998	AU 7256798 A	24-11-1998